September 20, 2019

Ms. Pamela Stutch, Attorney
Consumer Health Care Division
Bureau of Insurance
#34 State House Station
Augusta, ME 04333-0034

Via email: Pamela.Stutch@maine.gov

Re: Pharmacy Benefit Manager Rulemaking – Comments on Stakeholder Discussion

Dear Ms. Stutch:

I am writing to provide the Pharmaceutical Care Management Association (PCMA) comments on the Maine Bureau of Insurance's informal proposed rule on LD 1504, enacted earlier this year. PCMA is the national trade association representing pharmacy benefit managers (PBMs), which manage prescription drug benefits for large employers, health insurance carriers, labor trusts, government programs, and other payers. We appreciate the willingness of Bureau staff to take feedback from stakeholders and continue an open dialogue. At the meeting Sept. 9, the Bureau highlighted a few areas on which it was seeking input from stakeholders. We provide comment on those areas below and are happy to discuss further.

Licensure

Section 4348 of LD 1504 requires a PBM to obtain a license to act as a PBM in the State, by providing specified information. The law allows the superintendent to issue a PBM license only upon satisfaction that the applicant possesses the organization, expertise, and financial integrity to supply the services.

PCMA suggests that the Bureau look to the Tennessee license application as a starting point because it closely aligns with the Maine licensure law.[1] Both require basics such as name, address and contact information, and information about organization and financial integrity. In addition to what the Tennessee application requires, the Bureau's application would need to include the name and address of the company's agent for service of process (Sec. 4348(1)(C)), the name and address of individuals beneficially interested in the applicant (Sec. 4348(1)D)), and the name and address of each person with management and control over the applicant (Sec. 4348(1)(E)). Given that some of these companies are very large, it is important that the number of individuals to be listed be reasonable and truly reflect those who exert control over the company.

[1] The Tennessee Department of Insurance PBM Application can be viewed here: https://www.tn.gov/content/dam/tn/commerce/documents/insurance/forms/PBM_Licensing_Packet.pdf.

PCMA suggests that like the Tennessee application, audited, consolidated financial statements to demonstrate financial integrity, articles of incorporation to demonstrate the organization, and officer bios to demonstrate expertise could be required by the Maine application (Sec. 4348(2)). Again, the number of bios should be reasonable and reflect those truly in control of the organization's activities. PCMA suggests a $50 application review fee, consistent with Tennessee.

At the Sept. 9 meeting, the Bureau indicated that it had looked at Arkansas' or Kentucky's PBM license applications as a potential starting point. PCMA believes that these two states have laws that are unique to the circumstances in their particular states, and do not reflect what Maine has enacted. In addition, several of the sections of the underlying law that also created the Arkansas licensure requirement are the subject of litigation and, as of June 2018, overturned by the 8th Circuit, because they are preempted by ERISA and Medicare.[2] Again, PCMA encourages the Bureau to look to the Tennessee example as a place to start.

Fiduciary Duty

We appreciate the discussion of fiduciary duty at the Sept. 9 meeting and willingness to hear stakeholder comments. PCMA continues to have serious concerns over this requirement, as we indicated during the legislative process. We provide a brief analysis of the legal basis for our concerns below and are happy to discuss further if needed.

According to the U.S. Department of Labor (DOL) and federal courts,[3] PBMs are not fiduciaries. ERISA defines the term "fiduciary" as a person who (i) exercises any discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets or (ii) has any discretionary authority or discretionary responsibility in the administration of such plan."[4] The DOL has said that "Third Party Administrators (TPAs)," (which PBMs are) "who have no power to make any decisions as to plan policy, interpretations, practices or procedures, but who perform [certain] administrative functions for an employee benefit plan…are not fiduciaries of the plan."[5] The U.S. Supreme Court has ruled that a person is a fiduciary for an ERISA plan only "to the extent" a person "has or exercises such discretionary authority or control on behalf of a plan."[6] Following this decision, multiple federal courts have ruled that the PBM was not acting in a fiduciary capacity in managing its PBM-related services (e.g., negotiating with drug manufacturers or retail pharmacies or managing its formulary), but rather managing its own business which did not involve the discretionary control of plan assets.[7]

[2] PCMA v. Rutledge, 891 F.3d 1109 (8th Cir. 2018).
[3] Pharm. Care Mgt Ass'n v. District of Columbia, 613 F.3d 179 (D.C. Cir. 2010).
[4] 29 U.S.C. § 1002(21)(A).
[5] 29 CFR 2509.75-8 - Questions and answers relating to fiduciary responsibility under the Employee Retirement Income Security Act of 1974.
[6] Pegram v. Herdrich, 530 U.S. at 223, 120 S. Ct. 2143.
[7] *See* Chicago District Council of Carpenters Welfare Fund. v. Caremark, 474 F.3d 463, (7th Cir. 2007); *see also* Moeckel v. Caremark, Inc., 622 F. Supp. 2d 663 (M.D. Tenn. 2007), and In re Express Scripts/Anthem ERISA Litigation, 2018 WL 339346 (S.D.N.Y. Jan. 5, 2018).

Imposing fiduciary duties, as contemplated by ERISA, on PBMs would raise drug benefit costs by increasing PBMs' legal liability because of the greater potential legal exposure that exists as an entity that exerts control over plan assets (as opposed to one that merely administers a plan, within the benefit parameters established by the plan sponsor). It could also undermine PBMs' ability to effectively implement cost management tools for their clients, increasing projected drug expenditures by an estimated 5.8% over the next 10 years, or $309 million just in Maine.[8]

Pharmacy & Therapeutics Committees

Section 4350-B establishes requirements for individuals serving on carrier or PBM pharmacy and therapeutics (P&T) committees. As you know, P&T committees are responsible for making decisions for the PBM or carrier as to which FDA-approved drug options should be added to or removed or from the formulary. Carriers and PBMs agree that P&T committee members should be free from conflicts of interest on formulary decisions and have extensive processes in place to that end.

To help prevent decisions based strictly on cost to the PBM or carrier, the individuals on the P&T committees are typically not employed by the carrier or the PBM. The practitioners selected for serving on a P&T committee are often experts in their medical or pharmacy fields, or actively working in the research field. Often, they are highly-sought after experts, may serve as expert witnesses in legal proceedings, or may work for universities or medical schools that receive funding from manufacturers. This means that they may have received some sort of compensation, directly or indirectly, from a pharmaceutical-affiliated entity. Thus, a strict interpretation of LD 1504 may result in carriers or PBMs having to restructure P&T committees to serve only Maine and forego including practitioners that are experts in their fields in favor of practitioners who are less qualified.

The Centers for Medicare & Medicaid Services (CMS) has addressed this issue, and recently revised its procedures for the Medicare Part D program (prescription drug benefits), acknowledging the need to balance being cost-neutral and avoiding inappropriate influence with the need to have experts in their fields and who may receive compensation from a host of different types of health care entities. Ultimately, CMS established a requirement that a P&T committee must have at least one practicing physician and one practicing pharmacist, each who is independent and free of conflict relative to the Part D plan sponsor and pharmaceutical manufacturers.[9] Committee members are required to sign conflict of interest statements revealing any economic or other relationships affected by drug coverage decisions that could influence committee decisions. In the event a conflict arises for any member, CMS provides for the ability for that individual to recuse him or herself from decision-making around the particular drug in question. Federal rules relating to ACA plans' essential health benefits are similar.[10]

[8] "Increased Costs Associated With Proposed State Legislation Impacting PBM Tools," Visante, January 2019.
[9] 42 CFR Sec. 423.120(b)(1); Centers for Medicare and Medicaid Services, Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements, Section 30.1, *available at*: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf.
[10] 45 CFR Sec. 156.122(3) requires that P&T committee must: (a) have members that represent a sufficient number of clinical specialties to adequately meet the needs of enrollees; (b) consist of a majority of individuals who are

PCMA suggests that the Bureau adopt an interpretation of Section 4350-B that is consistent with CMS standards for conflicts of interest, by requiring at least practicing pharmacist and one practicing physician completely free of potential conflict, and creating a method of recusal in the event a member of a P&T committee has received some sort of compensation disallowed by the statute. Recusing oneself from decision-making on the particular drug in question would eliminate that member from "serving" on the P&T committee with respect to that drug, as Section 4350-B(2) requires.

Other Items

- Definition of "Carrier"

PCMA suggests clarification that self-insured, non-ERISA plans do not fall into the definition of "carrier."

- Definition of "Ingredient Cost"

At the Sept. 9 meeting, a stakeholder suggested that the term "ingredient cost" should be clarified to include the patient's cost-share amount. PCMA disagrees. The statutory definition of "ingredient cost" is appropriate.

- Section 4350(8)(C)

This section requires that the pharmacy provider that dispense the prescription drug be the only entity that may retain payment between a carrier or PBM and the pharmacy provider. PCMA members have identified this language as potentially vague and would like to discuss with the Bureau how it views the intent and potential implementation of this language.

Thank you for the opportunity to provide feedback on the issues above. We look forward to working with you as this proposal is developed. Please contact me at 202-756-5743 if you have any questions about our comments.

Sincerely,

April C. Alexander
Vice President, State Legislative and Regulatory Affairs

practicing physicians, practicing pharmacists and other practicing health care professionals who are licensed to prescribe drugs; (c) prohibit any member with a conflict of interest with respect to the issuer or a pharmaceutical manufacturer from voting on any matters for which the conflict exists, or (d) require at least 20 percent or its membership to have no conflict of interest with respect to the issuer any pharmaceutical manufacturer.